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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/230,111	05/17/99	SATO	T 48962-A-PCT-

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EXAMINER	
HOLLERAN, A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/230,111	Applicant(s) SATO ET AL.	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-76* is/are pending in the application.

4a) Of the above claim(s) *38,39,47-49,63,64 and 71-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-37,40-46,50-62,65-70,75 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species "a" in Paper No. 20 (filed 6/20/2001) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 27-76 are pending.

Claims 38, 39, 47-49, 63, 64, and 71-74, drawn to non-elected species, are withdrawn from consideration.

Claims 27-37, 40-46, 50-62, 65-70, 75 and 76 are examined on the merits.

3. Claims 27, 50, 52 and 75 are objected to for reciting an amino acid sequence that is not identified by a sequence identifier.

4. The specification is objected to for failure to comply with the sequence rules. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, claims 27, 50, 52, and 75 recite amino acid sequences that are not identified by a sequence identifier.

APPLICANT IS GIVEN THE TIME PERIOD OF THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with

these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Claim Rejections - 35 USC § 112

5. Claims 27-37, 40-46, 50-62, 65-70, 75 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 52 are indefinite because the claims recite detecting either a displaced protein or detecting a complex. However, there is no indication in the claims what the purpose is of detection of a complex.

6. Claims 27-37, 43-46, 50, 51, 52-62, 68-70, 75 and 76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for how to use methods of screening for compounds that disrupt the association between Fas and FAP, does not reasonably provide enablement for how to use methods of screening for compounds that disruspt the association between any cytoplasmic protein and signal transducing protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims..

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence

or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

The claims are broadly drawn to screening methods for the screening of compounds that disrupt the association between a cytoplasmic protein and a signal-transducing protein. The specification confines its teachings to how to screen for compounds that disrupt the binding of Fas with FAP. The prior art also teaches such methods, and also teaches that the use of such screening methods is to discover agents that may be used to modulate apoptosis. The basis for this teaching is that the prior art demonstrates that the association between Fas and FAP is a step that is required in signaling of apoptosis (see Reed et al, U.S. Patent 5,876,939, col. 29, line 10 – col. 30, line 47). The instant specification fails to teach how to use screening methods for all of the possible combinations of cytoplasmic protein and signal-transducing protein because the specification fails to teach the biological significance of any other combination, other than that of Fas with FAP. Thus, the specification appears to provide an invitation to research to discover uses of the most of the claimed screening assays. Therefore, it would require undue experimentation to first establish the biological significance of the association between a cytoplasmic protein and a signal-transducing protein, and then to use this information to know how to use the full scope of the claimed methods.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 27-37, 40-42, 50-62, 65-67, 75, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Reed et al (U.S. Patent 5,876,939; issued March 2, 1999; effective U.S. filing date March 27, 1995).

Reed discloses methods for screening for compounds that disrupt the binding of Fas (a signal transducing protein that is a receptor) with FAP (a cytoplasmic protein) (see column 13, line 51- column 14, line 6; and column 14, lines 18-20). The screening assay may be performed by a yeast two hybrid assay or by assay the level of a reporter gene (column 15, lines 13-27). The assay may be adapted for use in mammalian cells (column 15, lines 42-47). The compounds that may be screened are peptides, peptidomimetics, inorganic compounds, organic compounds (see column 13, lines 62-65). Reed discloses that Fas is expressed in breast, colon, and prostate cells (see column 1, lines 44-47). It is well known in the art that Fas is expressed in T-cells. Thus, Reed discloses methods of screening that are that claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
October 9, 2001

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